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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,766	02/18/2000	Shlomo Ben-Haim	BIO-95	8645

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Audley A. Ciamporcero Jr.
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No. 09/506,766	Applicant(s) BEN-HAIM ET AL.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-15 and 42-51 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claims 1, 12, 42 and 47 are vague since it is unclear if the sensor or another element, such as a processor, is actually “determining” the location of said non-contact electrodes defining a cloud of space and if this is a positive recitation of that determination and the “defining “ of a cloud of space. As relate to claims 1, 12, 42 and 47, the preamble claims a catheter for mapping, and the body appears to claim a larger system since there apparently is a signal generated and a location determined. The confusion is compounded because no signal generator for generating a signal and no signal processor to determine location of the non-contact electrodes are positively claimed. The scope of the claim must be clarified. Note that the concept of generating signals at a location sensor and determining the location of the non-contact electrodes amounts to an intended use limitation of which Ben-Haim et al. and Goldreyer perform or are inherently capable of performing.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. Claims 1-3, 7, 9, 10, 12, 13, 15-18, 22, 24, 25, 32-37, 39-45 and 47-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) in view of Goldreyer (US 5385146).

Ben Haim et al. disclose a method and apparatus to treat arrhythmias with ablation using one or more catheters (abstract). The tip of the catheter contains an electrode which can function at a site in the heart to sense electrical cardiac activity, to act as an antenna to deliver radio-frequency energy to perform ablation of tissue, or to deliver stimuli for pacing the heart (col. 11 @ 28-35). The electromagnetic location system in the tip of the catheter can contain between one and ten antennas to define the location of the tip area of the catheter (col. 11 @ 49-59). In figure 16, a tip electrode (105) and additional electrodes (106) are disclosed. The receiving antennas, located near the distal tip of the catheter (col. 12 @ 41-47), provide location information for the local activation data received from the tip electrode (105) and additional electrodes (106) (col. 7 @ 15-25; col. 10 @ 33-45; claims 30 and 31).

Ben-Haim et al. disclose the claimed invention except for:

- the electrodes being non-contact electrodes linearly arranged along a longitudinal axis of the catheter body, and
- the location of the non-contact electrode determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claims 1 and 2), determining a location of said contact electrode and a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contact electrode defines a cloud of space and determining a minimum volume of said heart chamber using the location of said non-contact electrodes (claims 16 and 35), at least one location sensor for determining a location of said contact electrode and location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a

minimum volume of the chamber of the heart (claim 42) and at least one location sensor for determining a location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 48).

Goldreyer discloses a catheter to sense extremely localized intracardiac electrical patterns.

As related to the non-contact electrodes arranged linearly, figures 1 and 2 disclose a catheter (10/32) including a stimulating tip (14) and non-contact electrodes (34-46) shown to be 14 electrodes, read to be about 16 electrodes (col. 5 @ 6-12). Goldreyer teaches an embodiment where the electrodes are non-contact (col. 2 @ 10-11) and are linearly arranged along a longitudinal axis of the catheter body to enable simultaneous sensing and ablation and/or pacing activity (col. 1 @ 55-59). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim et al., and provide electrodes being non-contact electrode linearly arranged along a longitudinal axis of the catheter body as taught by Goldreyer to enable simultaneous sensing and ablation and/or pacing activity so accurate and discrete mapping of the electrophysiologic activation within the heart is achieved (col. 1 @ 63 – col. 2 @ 4).

As related to the representation of the minimum volume of the heart chamber, Goldreyer teaches heart chamber mapping by sensing local cardiac signals in a minimal area of the heart chamber and repeating this process at predetermined positions within the chamber until accurate and discrete mapping of electrophysiologic activation within the heart is achieved

(col. 1 @ 55 – col. 2 @ 11), hence the definition of the minimum volume of the heart chamber is accomplished by defining the location of the activation data within the heart chamber by a location sensor as disclosed by Ben-Haim et al. and by the predetermined position of the non-contact electrodes on the catheter as taught by Goldreyer (col. 2 @ 38-42 and 51-56; col. 3 @ 53-60). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, and provide:

the location of the non-contact electrode determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claims 1 and 2), determining a location of said contact electrode and a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contact electrode defines a cloud of space and determining a minimum volume of said heart chamber using the location of said non-contact electrodes (claims 16 and 35), at least one location sensor for determining a location of said contact electrode and location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 42) and at least one location sensor for determining a location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 48)

as taught by Goldreyer to enable accurate and discrete mapping of electrophysiologic activation within the heart so optimal clinical treatment is provided to the patient (col. 1 @ 7-11).

The Applicant's arguments filed 1/29/03 have been fully considered, but they are not convincing.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Applicant asserts the Ben Haim et al. invention is directed toward determining lines or points of ablation and is not used to generate an electrical map of the heart chamber. The Examiner disagrees. Ben-Haim et al. provide an activation map of the heart/ define the physical dimensions or anatomy of the chamber to identify electrical pathways causing arrhythmia, both fixed pathways and not anatomically fixed, superfluous electrical pathways to enable the selection of ablation sites (col. 1 @ 64 – col. 2 @ 10; col. 5 @ 21-35; col. 6 @ 39-46), hence Ben-Haim et al. teach defining multiple clouds of space representing multiple minimum volumes of the chamber geometry of the heart as the electrical map is generated.

In response to the Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The rejection of record is deemed proper was not based on improper hindsight reasoning.

3. Claims 4-6, 14, 19-21, 26-31, 38, 46 and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) and Goldreyer (US 5385146) in view of Martinelli (US 6104944). As discussed in paragraph 2 of this action, modified Ben-Haim et al. disclose the claimed invention except for providing six degrees of location information using locations sensors in a proximate and a distal position relative to the electrode array.

Martinelli discloses a system and method for navigating a multiple electrode catheter and teaches that it is known to use two or more navigated electrode elements (N1-Nn), read as location sensors, between multiple virtually navigable electrode elements (E1-En), read as an array of non-contact electrodes (col. 4 @ 66 – col. 5 @ 8; col. 5 @ 24-33) to define the position of electrodes in a domain such as a chamber of the heart (col. 4 @ 63-66). Martinelli teaches the use of electromagnetic field sensors as the navigated electrode elements to provide navigational location information (col. 6 @ 18-32). The navigated electrode elements provide orientation and position coordinate data, read as the six degrees of location information (col. 6 @ 54-64; col. 8 @ 29-65), to establish the location of the virtually navigated electrodes and enable accurate mapping of the heart.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method and apparatus to treat arrhythmias with ablation as taught by modified Ben-Haim, providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array as taught by Martinelli to enable accurate mapping of the heart so arrhythmia producing cardiac tissue is identified and can be ablated.

The Applicant's arguments filed 1/29/03 have been fully considered, but they are not convincing. The Applicant asserts Martinelli does not provides five, not six degrees of freedom. The Examiner disagrees. Martinelli does provide for six degrees of freedom, the five noted by the Applicant, and a sixth degree of freedom which is a substantially zero component in the remaining axial/ sixth component (col. 8 @ 54-65).

4. Claims 8, 11 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (US 5718241) and Goldreyer (US 5385146) in view of Swanson et al. (US 6171306). As discussed in paragraph 2 of this action, modified Ben-Haim discloses the claimed invention except for the distal tip contact electrode being a bipolar electrode. Swanson et al. disclose an ablation catheter and teach that it is known to use a bipolar distal tip electrode to ablate the cardiac tissue (figure 5; col. 7 @ 11-14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by modified Ben-Haim, with a bipolar distal tip electrode as taught by Swanson et al. to utilize the electrodes in the device, the tip and the array electrodes, to ablate the tissue, eliminating the need for the addition of an external indifferent electrode (col. 7 @ 17-20). Utilizing a bipolar configuration also provides a more targeted ablating stimulus enabling more precise ablation.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JPO
3-25-03


ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700